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6 UNITED STATES DISTRICT COURT  
7 WESTERN DISTRICT OF WASHINGTON  
8 AT SEATTLE

9 WHIDBEY GENERAL HOSPITAL,

10 Plaintiff,

11 v.

12 MICHAEL O. LEAVITT, SECRETARY OF  
13 HEALTH AND HUMAN SERVICES

14 Defendant.

) CASE NO. C08-159 RSM  
)  
)

) ORDER DENYING PLAINTIFF'S  
) MOTION FOR SUMMARY JUDGMENT  
) AND GRANTING DEFENDANT'S  
) CROSS MOTION  
)

15 **I. INTRODUCTION**

16 This matter comes before the Court on the parties' cross motions for summary judgment  
17 (Dkt. #11 and #14). Plaintiff filed this action seeking judicial review of an administrative  
18 decision of the Secretary, in which the Secretary determined that Plaintiff was responsible for  
19 Medicare overpayments. Plaintiff argues that Defendant lacked the necessary jurisdictional  
20 authority to review the ALJ's decision, that Defendant's conclusion of fault was not supported  
21 by substantial evidence in the record and was based on improperly considered extra-record  
22 evidence, and that recovery or adjustment should be waived. Alternatively, if the Court  
23 determines that Plaintiff was at fault, Plaintiff argues that Defendant incorrectly determined the  
24 amount at issue.

25 Defendant asks the Court to uphold the Secretary's final decision and grant Defendant's  
26 motion for summary judgment as a matter of law based on the administrative record.

27 For the reasons set forth below, the Court agrees with Defendant. The Court DENIES  
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1 Plaintiff's motion for summary judgment and GRANTS Defendant's motion for summary  
2 judgment.

## 3 **II. DISCUSSION**

### 4 **A. Background**

5 This case arose from a disagreement between the Hospital and the Secretary, as  
6 represented by the Centers for Medicare and Medicaid Services ("CMS"), regarding  
7 reimbursements to the Hospital for its administration of the medication Pegfilgrastim ("Drug") to  
8 Medicare-eligible patients in 2004 through 2005.

9 Reimbursement procedures for administration of the Drug are included in the Federal  
10 Register ("Register"), which establishes payment procedures for Medicare providers. For this  
11 Drug, the 2004 Register contained two mutually exclusive rules. For administration in single  
12 dose vials, the Register advised that code J2505 be used for billing purposes. J2505 is defined as  
13 "Injection, Pegfilgrastim, per 6 mg, single dose vial," and billed at a rate of \$2596 per unit. For  
14 administration through different methods (such as pre-filled syringes), the Register advised that  
15 code APC 9119 be used for billing purposes. APC 9119 is defined as "Pegfilgrastim, per 1 mg,"  
16 and billed at a rate of \$2596 per unit.

17 The Register incorrectly stated the dosage amount associated with APC 9119. To remedy  
18 this mistake, CMS issued Transmittal 132 on March 30, 2004, which provided the correct dosage  
19 description of 6 mg, replacing the incorrect dosage description of 1 mg. Transmittal 132 was not  
20 included in the ALJ's record.<sup>1</sup>

21 Between January 2004 and May 2005, the Hospital administered the Drug through pre-  
22 filled 6 mg syringes to thirty-four patients. To receive compensation for these dosages, the  
23 Hospital billed for 6 units under APC 9119 for each 6 mg syringe dispensed. The Hospital,  
24 recognizing the disparity between the payment for a single-dose 6 mg vial under J2505 and the  
25 payment for a six-dose pre-filled syringe under APC 9119, contacted CMS to receive billing  
26 instruction clarification on September 6, 2005. On January 6, 2006, CMS informed the Hospital

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28 <sup>1</sup> Transmittal 132 was considered by the MEDICAL APPEALS COUNSICL ("MAC") as a result of its inclusion in  
CMS' Referral to the MAC for review. This transmittal was not challenged by the Hospital in its letter to the MAC  
responding to that Referral.

1 that APC 9119 in the Register contained a typographical error, improperly listing a dosage of 1  
2 mg, instead of 6 mg.

3 As a result of the Hospital's inquiry with CMS, Western Integrity Center ("WIC")  
4 audited the Hospital's claims, finding an overpayment of \$1,328,924.09. After two requested  
5 redeterminations, both Noridian Administrative Services, the Medicare intermediary, and First  
6 Coast Service Options ("First Coast"), the qualified independent contractor ("QIC"), similarly  
7 determined that the Hospital received an overpayment.

8 The Hospital next requested a hearing with an ALJ. The Hospital and First Coast were  
9 parties to the hearing. The ALJ found that the Hospital had overbilled for the Drug, but that the  
10 Hospital was not at fault for the errors. As a result, the ALJ held that no adjustment or  
11 recovery would be had against the Hospital.

12 A Medicare Administrative QIC, acting on behalf of CMS, referred this decision to the  
13 Medical Appeals Council ("MAC") for its own review. After review, the MAC found that the  
14 ALJ improperly concluded that the Hospital was without fault, and reversed. The MAC  
15 determined that the ALJ also improperly applied § 1870(c) to waive the Hospital's repayment  
16 of the overbilled amounts. The MAC's determinations served as the final decision of the  
17 Defendant Secretary. On January 31, 2008, the Hospital filed a Complaint for Judicial Review  
18 of Final Decision of Secretary of Health and Human Services in this Court.

19 The Hospital subsequently brought the instant motion for summary judgment, seeking  
20 reversal of the Secretary's decision. The Secretary filed a cross-motion for summary judgment,  
21 seeking dismissal of the Hospital's complaint and affirmation of the Secretary's final decision.

## 22 **B. Summary Judgment Standard**

23 Summary judgment is proper where "the pleadings, the discovery and disclosure  
24 materials on file, and any affidavits show that there is no genuine issue as to any material fact  
25 and that the movant is entitled to judgment as a matter of law." FRCP 56(c). In considering a  
26 motion for summary judgment, the court views all evidence in the light most favorable to the  
27 non-moving party. *Fairbank v. Wunderman Cato Johnson*, 212 F.3d 528, 531 (9th Cir. 2000).

1 The court must not weigh the evidence or determine the truth of the matter, but only  
2 determine whether there is a genuine issue for trial. *See Balint v. Carson City*, 180 F.3d 1047,  
3 1054 (9th Cir. 1999). The presence of a single genuine issue of material fact precludes summary  
4 judgment. *Cee-Bee Chem. Co. v. Delco Chem., Inc.*, 263 F.2d 150, 153 (9th Cir. 1959). An  
5 issue of fact is genuine if “the evidence is such that a reasonable jury could return a verdict for  
6 the non-moving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Material  
7 facts are those which might affect the outcome of the suit under governing law. *Id.*

### 8 **C. Standard of Review for Final Agency Decisions**

9 A party to a decision made by the MAC may seek judicial review of any final agency  
10 determination. *See* 42 C.F.R. § 405.1136. After consideration of the pleadings and transcript of  
11 record, the district court shall enter a judgment affirming, modifying, or reversing the agency’s  
12 final decision, with or without remanding the cause for a rehearing. 42 U.S.C. § 405(g).

13 The court considers the record in its entirety, “weighing both evidence that supports and  
14 evidence that detracts from the Secretary’s conclusion.” *Tackett v. Apfel*, 180 F.3d 1094, 1098  
15 (9th Cir. 1999) (citation omitted). “If the evidence is susceptible to more than one rational  
16 interpretation,” the court may not substitute its judgment for the agency’s. *Bear Lake Watch,*  
17 *Inc. v. FEC*, 324 F.3d 1071, 1086 (9th Cir. 2003). The Secretary’s factual findings, “if supported  
18 by substantial evidence, are conclusive.” 42 C.F.R. § 405.1136(f)(1). However, if not supported  
19 by substantial evidence or if based on legal error, the Secretary’s decision may be disturbed. *See*  
20 *Martinez v. Heckler*, 807 F.2d 771, 772 (9th Cir. 1986).

21 A court reviews administrative questions of law, including an agency’s interpretation of a  
22 statute, de novo. *Reynoso-Cisneros v. Gonzales*, 491 F. 2d 1001, 1002 (9th Cir. 2007).

23 Although courts give deference to the agency’s interpretation of relevant Medicare statutes and  
24 regulations, if its interpretations are inconsistent with those statutes and regulations, they will not  
25 be upheld. *County of Los Angeles v. Sullivan*, 969 F.2d 735, 740 (9th Cir. 1992).

26 A court reviews factual findings under the substantial evidence standard. *Alaska Dept. of*  
27 *Health and Soc. Servs. v. Ctrs. for Medicare and Medicaid Servs.*, 424 F.3d 931, 938 (9th Cir.  
28 2005). Substantial evidence is “more than a mere scintilla but less than a preponderance.”

1 *Tackett*, 180 F.3d at 1098 (citation omitted). It is “evidence that a reasonable mind might accept  
2 as adequate to support a conclusion.” *Richardson v. Perales*, 402 U.S. 389, 402 (1971).

3 **D. The MAC’s Jurisdictional Authority under 42 C.F.R. § 405.1110**

4 42 C.F.R. § 405.1110(c) sets out the standard of review for cases referred to the MAC. If  
5 CMS refers a case to the MAC when CMS did not participate in or was not a party to the ALJ  
6 proceeding, “the MAC will accept review if the decision... contains an error of law material to  
7 the outcome of the case.” 42 C.F.R. § 405.1110(c)(2).

8 If CMS refers a case when CMS or its contractor participated in the ALJ appeal, the  
9 MAC’s jurisdictional authority expands, allowing review on two additional grounds: (1) where  
10 the ALJ committed an abuse of discretion, and (2) where the decision is not consistent with the  
11 preponderance of the evidence of record. 42 C.F.R. § 405.1110(c)(1). Under this standard, “the  
12 MAC will limit its consideration of the ALJ’s action to those exceptions raised by CMS.” *Id.*

13 In this case, the Hospital asks the Court to analyze the MAC’s jurisdictional authority  
14 under the narrow standards of 42 C.F.R. § 405.1110(c)(2), arguing that CMS or its contractor did  
15 not participate in the ALJ proceeding. The record indicates that First Coast, the QIC contacted to  
16 reconsider the initial claims review, was a participant in the ALJ proceeding. (Pl.’s Excerpts R.  
17 23). The Hospital contends, however, that First Coast is not a CMS “contractor” within the  
18 meaning of the regulation, and thus the narrower standard applies.

19 The Court finds the Hospital’s argument unconvincing. The regulations expressly state  
20 that “CMS and/or one or more of its contractors, *including a QIC*, may also elect to participate in  
21 the [ALJ] hearing process.” 42 C.F.R. § 405.1010(a) (emphasis added); *see also* 42 C.F.R. §  
22 405.1000(c) *and* 42 C.F.R. § 405.1012(a). Moreover, by definition, a QIC is “an entity which  
23 *contracts* with the Secretary... to perform reconsiderations.” 42 C.F.R. § 405.902 (emphasis  
24 added). Thus, the Court finds that First Coast is a CMS contractor who participated in the ALJ  
25 proceeding.

26 Therefore, because CMS was a participant to the ALJ proceeding, the MAC had  
27 expanded jurisdictional authority to review the ALJ’s decision for an error of law and to  
28 determine whether the ALJ’s factual findings were consistent with the preponderance of the

evidence of record. Thus, the MAC had authority to review whether the Hospital was without fault and whether § 1870(c) may be considered to permit waiver of the overpayment. Before a discussion of these two issues, as a preliminary matter, the Court addresses the scope of the MAC's review.

### **1. Materials Outside of the Administrative Record**

Generally, the court will not consider an objection that was not raised below. *The Golden Gate Knutsen v. Associated Oil Co.*, 52 F.2d 397, 399-400 (9th Cir. 1931). A party waives his right to complain about the admission of evidence on appeal if he failed to object to the admission of the evidence on the trial record and to seek a ruling on the objection. *Fenton v. Freedman*, 748 F.2d 1358, 1360 (9th Cir. 1984).

There are three exceptions to the general waiver rule. *Romain v. Shear*, 799 F.2d 1416, 1419 (9th Cir. 1986). A court may review arguments raised for the first time on appeal "(1) in an 'exceptional' case when review is necessary to prevent a miscarriage of justice or to preserve the integrity of the judicial process, (2) when a new issue arises while appeal is pending because of a change in law, or (3) when the issue is purely one of law and the facts are fully developed." *Id.*

In reviewing an ALJ's determination, the MAC may only consider "the evidence contained in the record of the proceeding before the ALJ." 42 C.F.R. § 405.1122(a)(1). In this case, the MAC's review went beyond the scope of the administrative record, additionally reviewing new evidence, including Transmittal 132/Change Request ("Transmittal 132") and a "Medlearns Matters" article from December 2003 that CMS claimed indicated the correct billing for the Drug. The Hospital contends that the MAC improperly considered this new evidence to conclude that the Hospital was at fault for the overpayment.

Despite the regulation's requirement that the MAC consider evidence in the record only, because the Hospital raised an objection to this new evidence for the first time at the district court level, instead of during the MAC's review, the Hospital waived its right to be heard on this issue. None of the waiver exceptions apply. This is not an "exceptional case," no laws have changed pending appeal, and the issues at hand involve factual matters, not issues purely of law.

1 Accordingly, the Court will not overturn the MAC's determinations because of its consideration  
2 of extra-record evidence.

## 3 **2. Determination as to the Hospital's Fault**

4 After its review, the MAC agreed with the ALJ's finding that the Hospital received an  
5 overpayment, but reversed the ALJ's finding that the Hospital was "without fault," asserting that  
6 the Hospital had no reasonable basis for assuming that the payments it received were correct.  
7 The Hospital contends that substantial evidence did not exist to support the MAC's finding of  
8 fault.

9 The MAC relied on the two conflicting billing methodologies listed in the Register,  
10 Transmittal 132, and the Medicare Financial Management Manual, along with the administrative  
11 record, in making its determination. The Secretary contends that, considered together, these  
12 documents provided substantial evidence which a reasonable person might accept as adequate to  
13 support the conclusion that the Hospital was at fault.

14 The Court agrees with the MAC. Transmittal 132, standing alone, was enough to put the  
15 Hospital on notice of its incorrect billing practices. That transmittal clarified that the description  
16 listed for APC 9119 was incorrect; it stated that the new billing description should apply "per 6  
17 mg," instead of "per 1 mg." Moreover, the fact that the August 2003 proposed rule listed APC  
18 9119 as billed per 1 mg at a rate of \$467.09, a cost nearly one-sixth of the Register's instruction,  
19 indicated a potential error of which the Hospital reasonably should have been aware.

20 Similarly, considering the billing instructions in the Register alone, the Hospital should  
21 have made an inquiry to receive proper billing guidance. These conflicting billing instructions  
22 reasonably should have alerted the Hospital that it may have utilized the wrong billing unit.

23 Even though the Hospital makes a case that the ALJ properly decided in its favor,  
24 because the evidence is susceptible to more than one rational interpretation, this Court is  
25 compelled to accept the judgment of the MAC. *See Bear Lake*, 324 F.3d at 1086. Moreover,  
26 because the Secretary's finding of fault was supported by substantial evidence and because the  
27 Hospital waived its objection to the inclusion of evidence outside of the administrative record,  
28 the Court will not substitute its own view of the evidence for that of the MAC.

1                   **3. § 1870(c) Waiver Standard**

2                   Because substantial evidence supported the MAC’s finding that the Hospital was at fault,  
3 the Court finds that the waiver provisions of § 1870 of the Social Security Act, which only apply  
4 to “without fault” situations, are inapplicable to the case at hand.

5                   **E. Determination of Overpayment Amount**

6                   Just as a court will not review arguments raised for the first time on appeal, where a party  
7 conceded an issue below, the court will not review arguments regarding that conceded issue.  
8 *Pye v. Mitchell*, 574 F.2d 476, 480 (9th Cir. 1978). In cases where a party makes judicial  
9 admissions, the court prohibits that party from making contradicting arguments on appeal. *See*  
10 *American Title Ins. Co. v. Lacelaw Corp.*, 861 F.2d 224, 226 (9th Cir. 1988). Judicial  
11 admissions are “formal admissions in the pleadings which have the effect of withdrawing a fact  
12 from issue and dispensing wholly with the need for proof of the fact.” *Id.* Judicial admissions  
13 are “conclusively binding on the party who made them.” *Id.*

14                  However, when the argument involves questions of subject matter jurisdiction, a court  
15 may review the argument because these jurisdictional arguments are “non-waivable and may be  
16 raised at any time, including on appeal.” *Detabali v. St. Luke’s Hosp.*, 482 F.3d 1199, 1202 (9th  
17 Cir. 2007). Whether a claim is “jurisdictional” depends on whether the claim can be resolved by  
18 examining the relevant statute or the record without requiring further proceedings. *See United*  
19 *States v. Caparell*, 938 F.2d 975, 977-78 (9th Cir. 1991).

20                  The jurisdictional question in this case is whether CMS’s contractor had jurisdiction to  
21 include claims “extending more than a year prior to November 2005, when the Hospital was first  
22 informed that its claims... were to be reopened.” (Pl.’s Mot. Summ. J. 16). Because this  
23 question is jurisdictional in nature, the Hospital has not waived this argument and may object for  
24 the first time on appeal. However, the Hospital’s current objection is inconsistent with its  
25 previously asserted position. In its Post-Hearing Brief submitted after the ALJ proceeding, the  
26 Hospital conceded that the overpayment amount at issue was \$1,328,924.09. (Pl.’s Excerpts of  
27 R. 46). Thus, the Court need not consider the Hospital’s objection, as the admitted fact of the  
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1 overpayment amount is a previous judicial admission which “[withdrew the] fact from issue and  
2 dispens[ed] wholly with the need for proof of the fact.” *American Title*, 861 F.2d at 226.

3 **III. CONCLUSION**

4 Having reviewed the relevant pleadings and the remainder of the record, the Court  
5 hereby finds and ORDERS:

6 (1) Plaintiff’s Motion for Summary Judgment (Dkt. #11) is DENIED.

7 (2) Defendant’s Motion for Summary Judgment (Dkt. #14) is GRANTED, and the  
8 decision of the MAC is AFFIRMED. Plaintiff is DIRECTED to repay the Medicare  
9 overpayment amount of \$1,328,924.09 related to Plaintiff’s treatment of patients with the  
10 Drug between January 1, 2004, and May 31, 2005.

11 (3) The Clerk is directed to forward a copy of this Order to all counsel of record.

12 DATED this 29 day of April, 2009.

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15 RICARDO S. MARTINEZ  
16 UNITED STATES DISTRICT JUDGE  
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